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Section 2, HFASB (H7509C)

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DATA EVALUATION REPORT V

STUDY TYPE: Primary dermal irritation in rabbits — TOX CHEM NO. 309BB

MRID NO: — ACC. NO: 408064-6

TEST MATERIAL: TD 2073 (97.0%)

SYNONYMS: Potassium 3,4-dichloro-5-isothiazole carboxylate
AC 303,358 Chemical Hybridizing Agent; CHEMBRED

STUDY NUMBER(S): WIL-75019

SPONSOR: Pennwalt Corporation
Agrichemical Division
P.O. Box 1027
Puyallup, Washington 98371

TESTING FACILITY: Wil Research Laboratories, Inc.
Ashland, Ohio 44805-9281

TITLE OF REPORT: Primary Dermal Irritation Study in Albino Rabbits with TD 2073

AUTHOR(S): Naas, D. J.

REPORT ISSUED: 1/9/86

CLASSIFICATION: Core minimum data (Toxicity Category III)

CONCLUSIONS:

1. This study adequately defines the dermal irritation potential of technical TD 2073. The technical material is in toxicity category III, with a PDIS = 0.6, in terms of its dermal irritation hazard potential.

A. MATERIALS:

1. Test compound: TD 2073, 97.0%, lot no. N.B. 86-58-1. Described as on off-white powder.

2. Animals used: New Zealand white rabbits from Hazelton-Dutchland, Inc., Denver, PA. The body weights ranged from 3447 to 3763 g on the day of dosage.

B. STUDY DESIGN:

1. Test material administration: There was a 4-hr occluded dermal exposure to aliquots of 0.5 gm of the test material; each aliquot was moistened with about 0.4 ml deionized water. There was one test site on the intact dorsal skin of each of 6 rabbits.

2. Quality assurance: There is a signed and dated Good Laboratory Practices Compliance Statement on p. 3 of the report, which states: "The submitter of this study was neither the sponsor of this study nor conducted it, and does not know whether it has been conducted in accordance with 40 CFR Part 160." There is a laboratory Quality Assurance Unit Statement on p. 16.

C. METHODS AND RESULTS:

1. Observations: Test sites were evaluated (and scored by the criteria of Draize) at about 30 minutes after bandage removal and again at 24, 48, 72 and 96 hrs after dosage. Individual animals were terminated on days 3 or 4.

Results:

Only erythema (maximum score = 1) was observed. This had cleared in 4/6 rabbits by 72 hrs and had cleared in the remaining 2 by 96 hrs.

D. DISCUSSION:

The study defines a relatively low degree of dermal irritation potential for the technical material, with only a low grade of irritation (maximum Draize score = 1) following 4-hr occluded exposure. All dermal sites scored zero by day 4.

The study is classified as core minimum data.